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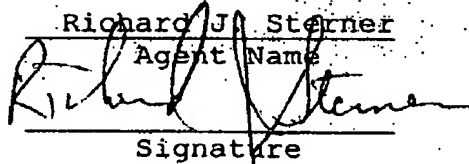
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Applicant : A. Bayati  
Serial No. : 10/053,279 Examiner: Michael Hartley  
Filed : January 17, 2002 Group Art Unit: 1616  
For : THERAPY FOR FUNCTIONAL DYSPEPSIA

OCT 15 2004

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	October 15, 2004
Signature	Date of Signature

Attn: Examiner M. Hartley

Art Unit: 1616

Facsimile No.: 703-872-9306

No. of pages: 22

Commissioner for Patents  
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INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with 37 CFR §1.56 and in accordance with 37  
CFR §§1.97 and 1.98, it is requested that the two (2) references  
listed on the attached Form PTO/SB/08A be made of record in this  
application. Copies of the references are enclosed.

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In accordance with 35 CFR §§1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made or that the information is material to patentability as defined in 37 CFR §1.56(b).

The two references cited herein are the Master of Science Thesis of Maria Nordling and an abstract thereof. The abstract was printed and copies were distributed to appropriate faculty members at the University of Uppsala. The thesis itself was presented orally to approximately ten people. The thesis was not distributed, nor was it housed or cataloged in the University library.

These documents are submitted under 37 CFR \$1.97(c), i.e., after the mailing of a first Office Action but prior to the mailing of a final Office Action. The Commissioner is hereby authorized to charge the fee set forth in 37 CFR \$1.17(p) to Deposit Account No. 23-1703. Any other fees which may be due for any reason in connection with this communication may likewise be charged.

Dated: October 15, 2004

Respectfully submitted,



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Enclosures



## Abstract

Functional dyspepsia (FD) is characterized by nausea, vomiting, bloating, feelings of fullness early satiety and epigastric pain, but the pathology is unknown. In many of the FD-patients, the proximal stomach is unable to relax in response to food. In others, the gastric motility or gastric emptying is impaired. Almost all of the FD patients report that they have been exposed to one or more social stressors for more than a year. It has been shown that stress alters the motility, and it may have altered the gastric motility in FD patients, leading to dyspeptic symptoms.

In order to investigate if stress also affects gastric accommodation in animals, the gastric volume response to balloon distension was compared in Sprague Dawley (SPRD) male and female rats and Wistar Kyoto (WKY) male rats, the latter being a rat very sensitive to stress.

A barostat system was coupled to a balloon, which was inserted into the stomach of the rat via a fistula. The barostat system was then connected to a program which produced the desired pressure: 10 min ramp distension up to 10 mmHg followed by 10 min tonic distension at 10 mmHg and then a decrease to 1 mmHg (the same as the starting pressure). The pressure and volume from the experiments were entered in a data program, and different parameters were then calculated from these data.

There were no significant differences between the groups in the basal tone or elasticity in the stomach muscle. Neither were there any significant differences between the groups regarding the threshold values when the adaptive reflex-mediated relaxation had started. It was also shown that there were no significant differences in any of the parameters between the SPRD female and male rats. However the adaptive relaxation was significantly impaired in WKY rats compared with both the SPRD male and female rats.

It was shown that the properties of the stomach muscle basal tone and tension were not impaired in WKY rats. The adaptive relaxation in response to distension was, on the other hand impaired, which indicates a defect in the reflex pathway in WKY rats.

The results show that the WKY rat, which is considered to be very sensitive to stress, has impaired gastric relaxation in response to gastric distension. This is in agreement with the pattern seen in some dyspeptic patients who have impaired adaptive relaxation related to a meal.

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